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| 10/606,700 | 06/26/2003 | Chang-Hsing Liang | 8024-004-US | 5029 |
| 32301 | 7590 | 11/12/2004 | EXAMINER | |
| CATALYST LAW GROUP, APC 4330 LA JOLLA VILLAGE DRIVE SUITE 220 SAN DIEGO, CA 92122 | | | PESELEV, ELLI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,700

Applicant(s)

LIANG ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 3-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 21, 2004.

Applicant's election with traverse of Group I, claims 1-2 and 5-8 in the reply filed on October 21, 2004 is acknowledged. The traversal is on the ground(s) that the examiner has not shown that the inventions are independent or distinct as claimed and that there would exist a serious burden on the Examiner if all of the claims were examined in one application. This is not found persuasive because the compounds of Group I and compounds of Group II have different structural formulas and utilities, are classified in different areas and would require a separate search and examination .

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific aminoglycosides set forth in Table 1, page 110 of the specification and the treatment of bacterial infections with said compounds, does not reasonably provide enablement for prophylaxis, amelioration or treatment of bacterial infections, viral infection, cancer or a genetic disorder (claims 5-6) or for antiviral or antifungal activity (claim 7) or for preventing the growth of bacteria (claim 8). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Claims 1-2 and 5-8 encompass compounds having a large number of possible structural formulas having significant differences. For example, a person of ordinary skill in the art would not expect a compound having the structure (I) wherein X1 and X2 are O, Y1 and Y2 is a bond and R3 is a group of formula (II) wherein each of R6, R7, R8 and R9 is hydrogen to have the same utility as a compound having structure (I) wherein X1 and X2 are S, Y1 and Y2 are divalent linking groups having 20 carbon atoms, R3 is a group of formula (III) wherein each of R6, R7, R8 and R9 is a disaccharide of formula (II-1), wherein said disaccharides are further substituted by disaccharides. Note that all the compounds tested are limited to compounds wherein each of X1 and X2 is O and wherein formula (i) or (II) is substituted by a single disaccharide with no additional disaccharide substituents. Further, no evidence has been presented showing that the claimed compounds are effective in prophylaxis of bacterial infections. Note that the term "prophylaxis" encompass providing a vaccine. Since aminoglycosides are not known to be useful as vaccines, there is a good reason to doubt that the claimed compounds are effective as vaccines. Further, no evidence has been provided showing that the claimed compounds are effective in prophylaxis of viral infections, cancer or a genetic disorder or have antifungal activity.

(A) The breadth of the claims is such that it will require an undue experimentation by a person having ordinary skill in the art to determine which specific compounds possess the desired utility. It is well known in the art that even a small structural change can greatly affect the activity of a compound, while the instant claims encompass compounds having major structural differences as discussed above.

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(B) The nature of invention is such that it is directed to prophylaxis and treatment of cancer and genetic disorders while providing no guidance for the prophylaxis or treatment of which specific viral infections, cancers and genetic disorders the claimed compounds are useful. Due to the differing underlying causes which give rise to various cancers and genetic disorders and unpredictability of treating the same, there is a good reason to doubt that the claimed compounds are effective in prophylaxis of viral infections, cancer and genetic disorders.

(C) The state of the prior art is such that aminoglycosides such as gentamycin, streptomycin and kanamycin are known to be effective antibacterial agents but are not known for prophylaxis and treatment of viral infections, cancers and genetic disorders.

(D) The level of one of ordinary skill in the art is such that only a limited number of aminoglycosides are expected to possess antibacterial activity.

(E) The level of predictability in the art is such that a person having ordinary skill in the art at the time the instant was made would not expect compounds having very different structural formulas as encompass by the instant claims to possess the same utility. It would take an undue amount of experimentation by a person having ordinary skill in the art to determine which specific compounds, besides those set forth in Table I in the specification will have antibacterial activity. Further, there is no reason to suspect that the claimed compounds are effective in prophylaxis or treatment of viral infections, antifungal infections, cancers or genetic disorders.

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(F) The amount of direction provided by the inventor is non-existent as to specific viral infections, cancers and genetic disorders which can be treated with the claimed compounds.

(G) The existence of working examples is limited to a small number of compounds tested for antibacterial activity.

(H) The quantity of experimentation needed to make and use the invention based on the content of the disclosure is great.

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear whether claim 1 is a compound or a composition claim. Such terminology as "A compound having the structure of (I)" in the preamble can be used to overcome the rejection.

It is not clear what is encompassed by the terminology "modified amino" "modified hydroxyl", "modified amino" and "monoe" (all occurrences). Modified how? I.e. the scope of the invention cannot be determined.

Claim 6 is indefinite in that it is not clear to whom the compound of formula I is administered.

Claims 1 and 7 are substantial duplicates.

Claim 8 is improper in that it contains a period in the middle of the claim after the term "carrier".

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Regarding claims 1-2 and 5-8, the phrase "including" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps for synthesizing compounds having the structure of (I).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ghoshal et al (U.S. Patent No. 6,653,456).

Ghoshal et al disclose compounds encompassed by the instant claimed (see, for example, Figure 4, Figure 6 and Figure 8) and further teach in column 1 that aminoglycosides are effective antibacterial agents. The claimed compounds, composition and methods are anticipated by Ghoshal et al. In addition, if there are any differences between the claimed compounds and the prior art compounds, the differences would appear to be minor in nature and the claimed compounds, which fall within the scope of the prior art's disclosure, would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made.

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kondo et al (U.S. Patent No. 5,618,795).

Kondo et al disclose aminoglycoside antibiotics which are encompassed by the instant claims having antibacterial activity. The claimed compounds, composition and methods are anticipated by Kondo et al. In addition, if there are any differences between the claimed compounds and the prior art compounds, the differences would

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appear to be minor in nature and the claimed compounds, which fall within the scope of the prior art's disclosure; would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the instant invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev


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